

Certificate of Analysis

Productname: Acidum folicum hydricum
Number of analysis/Inspection Code: 4 / KEUR-193829B
Batchnumber: 21K29-F03-381232
Reference code / No.: 4192 / FX08/21-22
Analysed according to: PH.EUR10.6

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow or orange, crystalline powder	Conform		
Identification A	+18 - +22	+20	°	Specific optical rotation; anhydrous
Identification B	Conform	Conform		IR-spectrum
Identification D	5,0 - 8,5	Conform		Water
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	0,1	%	
Impurity D	<=0,4	0,1	%	
Impurity C	<= 0,3	<0,05	%	
Impurity E	<= 0,3	<0,05	%	
Impurity G	<= 0,3	<0,05	%	
Impurity H	<= 0,15	<0,05	%	
Impurity I	<= 0,15	0,10	%	
Unspecified impurities	<= 0,10	<0,05	%	
Total of other impurities	<=1,2	0,3	%	
Water (Karl Fischer)	5,0 - 8,5	6,7	%	
Sulphated ash	<= 0,2	0,2	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Folic acid	96,0 - 102,0	99,1	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
 Anthony Amoureux
 Qualified Person

03/02/22

Expiration: 06-2026

Conclusion: APPROVED

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